MAJOR REGULATIONS STANDARDIZED REGULATORY IMPACT ASSESSMENT SUMMARY

DF-131 (NEW 11/13)

STANDARDIZED REGULATORY IMPACT ASSESSMENT SUMMARY

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1. Statement of the need for the proposed major regulation.

The authority to regulate medical cannabis was granted in Assembly Bills (AB) 243, 266 and Senate Bill (SB) 643, which are collectively known as the Medical Cannabis Regulation and Safety Act of 2015 (MCRSA). AB 243 instructs the California Department of Public Health (CDPH) to develop standards for the production and labeling of edible and manufactured medical cannabis products. AB 266 defines the various terms and concepts within medical cannabis including "manufactured cannabis," which is "raw cannabis that has undergone a process whereby the raw agricultural product has been transformed into a concentrate, an edible product, or a topical product." SB 643 requires CDPH to incorporate certain provisions for the licensing of manufactured medical cannabis products, such as requiring the licensee to describe the extraction and infusion methods and submitting criminal background checks.

2. The categories of individuals and business enterprises who will be impacted by the proposed major regulation and the amount of the economic impact on each such category.

Current manufacturers of medical cannabis products and potential future manufacturers will face increased industry costs due to the proposed CDPH regulations of \$39.1 million or 14.8 percent of manufacturer sales to medical cannabis retail dispensaries starting in 2019. Consumers will benefit because there will be a noticeable fall in the risk premium after manufactured medical cannabis is regulated. The risk premium is the additional amount that must be paid to compensate individuals for working in an industry that faces risk of law enforcement action. The decrease in the risk premium will increase supply, offset regulatory costs, and keep prices for manufactured medical cannabis from rising with regulations.

3. Description of all costs and all benefits due to the proposed regulatory change (calculated on an annual basis from estimated date of filing with the Secretary of State through 12 months after the estimated date the proposed major regulation will be fully implemented as estimated by the agency).

The MCRSA regulatory costs to manufacturers of medical cannabis relate to labeling, testing, packaging, background checks, license fees, BOE seller's fees, bonding, local permitting, facility compliance and video surveillance, closed-loop production systems, standard operating procedures, general licensing requirements, unadulterated and serving size limits, and inventory control and security. In the first year of implementation we estimate costs to total \$51.9 million. In the second year and beyond, we expect annual industry costs to total \$39.1 million in inflation adjusted terms. The MCRSA regulatory benefits and costs of regulation are measured by the increase in consumer surplus (or well-being). Consumer surplus is the difference between the total amount that consumers are willing and able to pay for a good or service and the total amount that they actually do pay. The regulatory costs in 2019 and beyond are estimated to be \$315 million per year in reduced consumer surplus, while the regulatory benefits in 2019 and beyond are estimated to be \$317 million per year in increased consumer surplus. The net benefit per year is \$2 million.

4. Description of the 12-month period in which the agency estimates the economic impact of the proposed major regulation will exceed \$50 million.

An initial calculation was performed, and it was determined that it was likely that CDPH's proposed regulations on medical cannabis manufacturers would reach the \$50 million threshold for an economic impact within a 12-month period. We have refined the additional cost and impact calculations and estimate that in 2018, the year of initial implementation, increased direct costs to medical cannabis manufacturers will be \$51,856,163.

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5. Description of the agency's baseline:

We estimate that total retail sales of manufactured medical cannabis in California is \$651 million in Fall 2016 with sales from manufacturers to medical retail dispensaries totaling \$228 million. We estimate that there are 1,000 manufacturer and 4,140 workers and owners in the industry. The baseline for constructing the impact of MCRSA regulations takes into account the fact that the Adult Use of Marijuana Act of 2016 (AUMA), which creates a legal recreational cannabis market, will be implemented at the same time. If expected AUMA regulations were implemented in isolation, they would have the impact of lowering the price of manufactured recreational cannabis enough to reduce demand for manufactured medical cannabis to zero. The impact of MCRSA regulations is to restore about two thirds of the manufactured medical cannabis market.

- 6. For each alternative that the agency considered (including those provided by the public or another governmental agency), please describe:
 - a. All costs and all benefits of the alternative
 - b. The reason for rejecting alternative

Benefits and costs are measured in terms of changes in consumer surplus. The first alternative considered is to imprint a warning label to the manufactured product itself, in addition to the exterior label. This warning label is applied directly to the surface of the product, either by being marked, stamped, or imprinted. With this approach, we estimate that ongoing annual costs stemming from industry costs of regulation would equal \$398 million while ongoing annual benefits stemming from increased demand and reduced risk premium would equal \$387 million. This alternative was rejected because it was cost ineffective. Instead we choose a printed label that accompanies any medical cannabis product. A second alternative is to require Live Scan background checks for all participants (employees and owners) in a company. Instead we choose the statutory requirement that only the owners of a company need to have a Live Scan background check. We estimate that ongoing annual costs stemming from industry costs of regulation equal \$322 million while ongoing annual benefits stemming from reduced risk premium equal \$317 million. This alternative was rejected because it cost more to achieve the same benefits.

7. A description of the methods by which the agency sought public input. (Please include documentation of that public outreach).

CDPH, along with the Bureau of Medical Cannabis Regulation, conducted preregulatory stakeholders meetings to provide the public with an opportunity to participate in discussions on specific topics regarding dispensaries, distributors, manufacturers, testing laboratories, and transporters. The meetings were held in Redding, Sacramento, Santa Rosa, Oakland, Fresno, Los Angeles, San Diego, and Santa Ana during September and October 2016. Members of HIIMR attended over half of the meetings to solicit input from stakeholders and to compile a contact list for our survey. Announcements and materials were distributed at the meetins and posted on the CDPH Office of Manufactured Cannabis website: http://www.cdph.ca.gov/programs/Pages/OMCSStakeholderMeeting.aspx

8. A description of the economic impact method and approach (including the underlying assumptions the agency used and the rationale and basis for those assumptions).

Our approach is to determine how MCRSA and AUMA proposed regulations affect prices in the manufactured medical and recreational markets. Price changes stem from increased regulatory costs and decreases in the risk premium. We then use those price changes in our model of demand in medical, recreational, and illegal markets in order to determine quantity changes in each market. In addition to the costs specified above, we describe below other cost and market impacts of the regulations, and we divide them into supply and demand side effects. Since both MCRSA and AUMA are implemented at the same time, we calculate the marginal impacts of MCRSA by subtracting the stand alone impacts of AUMA from the combined impacts of MCRSA plus AUMA. With combined changes in the medical, recreational and illegal markets, we customized the the Impact Analysis for Planning (IMPLAN) Pro software to determine the impact on California Gross State Product and jobs. We also use the price and quantity changes to quantify consumer welfare benefits in terms of changes in consumer surplus. Those changes in surplus, the costs and benefits from the proposed regulations, and alternatives.

Agency Signature	Date
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